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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,979	08/08/2005	Jean-Noel Thorel	124461	9531

25944 7590 09/28/2009

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EXAMINER	
VU, JAKE MINH	
ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
09/28/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/540,979	THOREL ET AL.	
	Examiner	Art Unit	
	Jake M. Vu	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *2,4,16 and 19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5-13,15,17 and 18* is/are rejected.

7)☒ Claim(s) *14* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of Applicant's Restriction Requirement Response filed on 06/19/2009; and Amendments filed on 03/17/2009 and 06/16/2009.

- Claims 1 and 2 have been amended.
- Claims 1-19 are pending in the instant application.
- Claims 2, 4, 16 and 19 are withdrawn from consideration.

Election/Restrictions

Applicant's election with traverse of Group I (claims 1, 3, 5-15, 17-18) in the reply filed on 06/16/2009 is acknowledged. The traversal is on the ground(s) that Huth does not disclose any processes as claimed that utilize "a complex nutritive base...consisting of a multiplicity of amino acids, vitamins, trace elements, and metallic salts and being free of any cellular growth factor or any biological extract of animal or cellular origin or any pharmaceutically active principle" as recited in the claims of both Group I and Group II. While Huth may disclose compositions that include vitamins, Huth does not disclose and would not have rendered obvious the use of a complex nutritive base consisting of a multiplicity of amino acids, vitamins, trace elements, and metallic salts, and such a complex nutritive base that is free of any cellular growth factor or any biological extract of animal or cellular origin or any pharmaceutically active principle.. This is not found persuasive because HUTH does teach at least a multiplicity (which reads on 2 or more) of amino acids (see pg. 19, line 6-10); vitamins, such as vitamin E;

a metal salt, such as sodium; and trace elements, such as chloride (see pg. 42, Table 8).

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1, its unclear what process claim 1 is claiming and what is the need to applying the composition to the eye.

Additionally, it is unclear what the terms “free of pharmaceutically active principal”, “cellular origin”, and "biological extract of animal” encompasses, since vitamins are considered as pharmaceutics, amino acids are of cellular origin, and trace elements can be of biological extract of animals.

Regarding claim 5, the Examiner assumes the term "Osm" is incorrect and should be "mOsm". Please clarify.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, 5-7, 12, 13, 15, 17, 18 are rejected under 35 U.S.C. 102(a,e) as being anticipated by HUTH et al (WO 02/087326).

Applicant's claims are directed to a process comprising of: applying to the eye a composition comprising of: amino acids; vitamins; trace elements; and metallic salt; inhibitor of collagenases, such as N-acetylcysteine, promoter of neocollagen synthesis; preservatives, such as polyhexamethylene biguanide. Additional limitations include: pH between 7.3 and 7.5; osmolality between 300 and 350 Osm; liquid form; comfort solution.

HUTH teaches a process comprised of: applying to the eye (see abstract) a composition comprising of: amino acids (see pg. 19, line 6); vitamins (see pg. 10, line 32; pg. 42, Table 8); trace elements, such as chloride (see pg. 42, Table 8); and metallic salt, such as sodium (see pg. 19, line 15-17; pg. 42, Table 8); inhibitor of collagenases, such as N-acetylcysteine (see pg. 19, line 11), promoter of neocollagen synthesis, such as water (see pg. 45, Table 9); preservatives, such as polyhexamethylene biguanide (see pg. 43, Table 9). Additional disclosures include: pH of 7.45 (see pg. 28, line 5); osmolality between 320 mOsm (see pg. 29, line 9); liquid form and artificial tears, which

reads on comfort solution (see abstract); and disinfect contact lenses (see abstract); free of any pharmaceutically active components.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3, 5-13, 15, 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over HUTH et al (WO 02/087326) in view of HOZUMI et al (US 6,806,243) and LAURIE et al (US 7,320,870).

As discussed above, HUTH teaches a process comprised of: applying to the eye (see abstract) a composition comprising of: amino acids (see pg. 19, line 6); vitamins (see pg. 10, line 32; pg. 42, Table 8); trace elements, such as chloride (see pg. 42, Table 8); and metallic salt, such as sodium (see pg. 19, line 15-17; pg. 42, Table 8); inhibitor of collagenases, such as N-acetylcysteine (see pg. 19, line 11), promoter of neocollagen synthesis, such as water (see pg. 45, Table 9); preservatives, such as polyhexamethylene biguanide (see pg. 43, Table 9). Additional disclosures include: pH of 7.45 (see pg. 28, line 5); osmolality between 320 mOsm (see pg. 29, line 9); liquid form and artificial tears, which reads on comfort solution (see abstract); disinfect/clean contact lenses (see abstract); viscosity agents (see pg. 27, line 4).

HUTH does not teach using proline; hyaluronic acid; or in the amounts as claimed by Applicant.

HOZUMI teaches an ophthalmic solution or contact lens solution (see col. 1, line 11-18) comprised of: amino acids (see col. 18, line 59), such as proline (see col. 4, line 13; col. 19, line 40); a preservative, such as polyhexamethylene biguanide (see col. 18, line 67); sodium (see col. 19, line 8); and a thickening agent, such as a heteropolysaccharide (see col. 11, line 65-67), wherein the addition of amino acids improve the preservative effect.

LAURIE teaches common ingredients in ophthalmic compositions include: surfactants, preservatives, antioxidant agents, such as vitamin E, and viscosity agents, such as hyaluronic acid (see col. 10, line 11-26 and line 48-52).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate vitamin E, amino acids, such as proline; and viscosity agents, such as hyaluronic acid into HUTH's composition. The person of ordinary skill in the art would have been motivated to make those modifications, because the vitamin E and proline would increase the antioxidant/preservative effect and the hyaluronic acid could adjust the viscosity of the solution to optimize delivery of the solution to the eye, and reasonably would have expected success because HUTH teaches using amino acids and viscosity agents.

The references do not specifically teach adding the ingredients in the amounts claimed by Applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely

optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results, the preservative effect and viscosity of the solution. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of Applicant's invention.

Claim Objections

Claim 14 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in PROPER independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Telephonic Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jake M. Vu whose telephone number is (571)272-8148. The examiner can normally be reached on Mon-Tue and Thu-Fri 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/
Primary Examiner, Art Unit 1618